

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

) THIS DOCUMENT RELATES TO:)
))
SHEILA BROWN, et al.)) CIVIL ACTION NO. 99-20593
v.))
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.

8882

Bartle, J.

May 30, 2012

Janice Eakle ("Ms. Eakle" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Dennis L. Eakle, Ms. Eakle's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In August, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Allan P. Latcham, M.D., F.A.C.C. Dr. Latcham is no stranger to this litigation. According to the Trust, he has signed at least 138 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated July 1, 2002, Dr. Latcham attested in Part II of Ms. Eakle's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial

3. (...continued)

Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

dimension, and a reduced ejection fraction in the range of 50% to 60%.⁴ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$538,973.⁵

In the report of claimant's echocardiogram, Dr. Latcham noted that claimant had "moderate mitral valve regurgitation with the mitral valve area to left atrial area ratio of 20.55%." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the regurgitant jet area ("RJA") in any apical view is equal to or greater than 20% of the left atrial area ("LAA"). See Settlement Agreement § I.22.

In September, 2005, the Trust forwarded the claim for review by Issam A. Mikati, M.D., one of its auditing cardiologists.⁶ In audit, Dr. Mikati determined that there was no reasonable medical basis for the attesting physician's finding

4. Dr. Latcham also attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition, however, is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of the five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of a reduced ejection fraction, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

6. Claimant incorrectly identifies the auditing cardiologist as Rohit Parmer, M.D., who is an employee of Baylor University Medical Center.

that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Mikati stated that claimant had "[m]ild [regurgitation]. Backflow was traced to [inflate the mitral regurgitant] jet so that it reaches [moderate mitral regurgitation]."

Based on the auditing cardiologist's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Eakle's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁷ In contest, claimant argued that the auditing cardiologist's review of the echocardiogram was flawed. In support of this argument, claimant submitted a letter from Waenard L. Miller, M.D., F.A.C.C.,⁸ who stated that Ms. Eakle had "moderate mitral regurgitation with RJA/LAA of 20%."

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Eakle's claim.

8. Dr. Miller is also no stranger to this litigation. According to the Trust, he has signed in excess of 2,872 Green Forms on behalf of claimants seeking Matrix Benefits.

The Trust then issued a final post-audit determination again denying Ms. Eakle's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Eakle's claim should be paid. On June 12, 2006, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6372 (June 12, 2006).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on August 31, 2006. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁹ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, James F. Burke, M.D., F.A.C.C., to review the

9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

The Technical Advisor, Dr. Burke, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Burke stated that:

Upon my review of the tape, my overall assessment of the mitral regurgitation is mild.

Using representative beats in the apical four chamber view, I calculated RJA/LAA

(regurgitant jet area/left atrial area) ratios to range from 5 to 10%. This represents mild mitral regurgitation.

Using representative beats in the apical two chamber view, I calculated RJA/LAA ratios to range from 6 to 11%. This represents mild mitral regurgitation.

Using representative beats in the apical three chamber view, I calculated RJA/LAA ratios to range from 4 to 7%. This represents mild mitral regurgitation.

I agree with the assessment of Issam Mikati, M.D. that the mitral regurgitant jet area was traced in an inflated method that included backflow.

In response to the Technical Advisor Report, claimant argues that Dr. Burke failed to address Dr. Miller's qualifications, and that Dr. Miller's findings should be given deference based on his qualifications. Claimant also notes that Dr. Miller never met claimant and that there is "literally no relationship between this doctor and the claimant...."

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not refute the specific determinations of the Technical Advisor. She does not challenge Dr. Burke's conclusion that "even taking into account inter-reader variability, I believe there is no reasonable medical basis for the [a]ttesting [p]hysician's answer to Green Form Question C.3.a., which states that [c]laimant suffers from moderate mitral regurgitation." On this basis

alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

Moreover, we disagree with claimant that Dr. Miller's letter establishes a reasonable medical basis for her claim. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here, both Dr. Mikati and Dr. Burke found that claimant's attesting physician improperly characterized backflow as mitral regurgitation. Such an unacceptable practice cannot provide a reasonable medical basis for the resulting diagnosis and the Green Form representation that claimant suffered from moderate mitral regurgitation.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral

regurgitation. Therefore, we will affirm the Trust's denial of Ms. Eakle's claim for Matrix Benefits and the related derivative claim submitted by her spouse.